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10/583,061

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EXAMINER

JANSSEN, SHANNON L

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,061	<b>Applicant(s)</b> GLIMCHER ET AL.	
	<b>Examiner</b> SHANNON JANSSEN	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

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### **DETAILED ACTION**

Claims 1-47 are currently pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3, and 6-14, drawn to a method for identifying a compound that modulates cytokine production comprising identifying a compound that modulates PMRT1.

Group II, claim(s) 2, drawn to a method for identifying a compound that modulates T-cell production comprising identifying a compound that modulates PMRT1.

Group III, claim(s) 4-5, drawn to a method for identifying a compound that interacts with PMRT1 by detecting expression of a reporter gene.

Group IV, claim(s) 15-19, drawn to a method of identifying compounds that modulate the activity of NIP45.

Group V, claim(s) 20-32, drawn to a method comprising identifying compounds that activate various promoters, such as IL-4, IFN- $\gamma$ , ERG2, ERG3, c-Rel, and p65.

Group VI, claim(s) 33-41 drawn to a method comprising identifying compounds that modulate the interaction of PMRT1 and NIP45.

Group VII, claim(s) 42-47, drawn to a method comprising identifying compounds that modulate expression of a reporter gene comprising treating a cell with an activator.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common technical feature is a method of identifying compounds that interact with/modulate PMRT1. The common technical feature is known in the art. For example, Tang et al. (Protein-arginine Methyltransferase I, the predominant protein-arginine methyltransferase in cells, interacts with and is regulated by interleukin enhancer-binding Factor 3, 2000, The Journal of Biological Chemistry, Vol 275, pp19866-

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19876) teaches methods comprising screening a plurality of cells comprising PMRT1 for compounds that interact with PMRT1 and further teach identifying compounds that modulate the activity of PMRT1 (see entire document, particularly Abstract and p 19867). In addition, Groups I-III and IV-VII have different technical features. The technical feature of Groups I-III is a method of identifying compounds that interact with/modulate PMRT1. The technical feature of Group IV is a method of identifying compounds that modulate the activity of NIP45. The technical feature of Group V is a method comprising identifying compounds that activate various promoters, such as IL-4, IFN- $\gamma$ , ERG2, ERG3, c-Rel, and p65. The technical feature of Group VI is a method comprising identifying compounds that modulate the interaction of PMRT1 and NIP45. The technical feature of Group VII is a method comprising identifying compounds that modulate expression of a reporter gene comprising treating a cell with an activator.

### *Species Election*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicants are requested to elect a single ultimate species of the following if **Group I** is elected:

A) A single ultimate species of indicator composition. For example, cell (as in claims 6-7 and 11-12) OR cell free (as in claim 8).

B) A single ultimate species of determining the effect of a compound on PMRT1 activity. For example, the ability to methylate a target protein (as in claim 9) OR a NIP45-related activity (as in claims 3, 10, and 13-14).

C) A single ultimate species of polypeptide further comprised. For example, NIP45 (claim 11) OR NFAT (claim 12).

Applicants are requested to elect a single ultimate species of the following if **Group IV** is elected:

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A) A single ultimate species of polypeptide further comprised. For example, PMRT1 (claim 16) OR NFAT (claim 17).

Applicants are requested to elect a single ultimate species of the following if **Group V** is elected:

A) A single ultimate species of indicator composition. For example, cell (as in claims 21-22) OR cell free (as in claim 27).

B) A single ultimate species of determining the effect of a first polypeptide. For example, measuring binding to NFAT (as in claim 22) OR measuring transcription from a promoter (as in claim 24).

C) A single ultimate species of detecting activity of the second polypeptide. For example, measuring methylation of NIP45 (as in claim 28) OR measuring the interaction of between the second polypeptide and the first polypeptide (as in claim 29).

Applicants are requested to elect a single ultimate species of the following if **Group VI** is elected:

A) A single ultimate species of readout of interaction between NIP45 and PMRT1. For example, binding of NIP45 to PMRT1 (as in claim 36) OR methylation of NIP45 (as in claim 36) OR modulation of gene expression (as in claim 37).

Applicants are requested to elect a single ultimate species of the following if **Group VII** is elected:

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A) A single ultimate species of promoter. For example, IFN- $\gamma$  (claim 43) OR IL-4 (claim 45).

B) A single ultimate species of activator of gene transcription. For example, T-bet (claim 44) OR NFATc2 (claim 46) OR NIP45 (claim 46).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Please refer to above species election for correspondence between the species and the claims.

The following claim(s) are generic: 1, 15, 20, 33, 42.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species lack the same technical feature because they do not share a common core structure and/or function and involve different methods.

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Applicant is advised that the reply to this requirement to be complete must include **(i) an election of a species or invention to be examined** even though the requirement may be traversed (37 CFR 1.143) and **(ii) identification of the claims encompassing the elected invention.**

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Future Communication***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANNON JANSSEN whose telephone number is (571)270-1303. The examiner can normally be reached on Monday-Friday 9:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/  
Primary Examiner, Art Unit 1639

Shannon L Janssen  
SLJ